K131984

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MAR 3 1 2014

6.0 - 510(k) Summary

Date Prepared: June 28, 2013

Sponsor:	Synthes Angela F. Lassandro 1301 Goshen Parkway West Chester, PA 19380 Office: (610) 719-6854 Fax: (484)-356-9682
Proprietary Name:	Synthes Synsonic Ulna Nail System
Classification:	Classification: 888.3020 Product Code: HSB
Predicate Device:	Synthes Titanium Elastic Intramedullary Nail System (K042135) Synthes Olecranon Osteotomy Nail System (K073402) Bonuttti Research, Inc. Unity Ultrasonic System (K090175)
Device Description:	The Synthes Synsonic Ulna Nail System consists of intramedullary nails with end caps and locking tacks designed to treat fractures of the ulna. The system makes use of an ultrasonic generator to deliver energy through a handpiece to securely fasten the locking tacks to the surface of the nail. The handpiece features a force sensor mechanism that provides feedback to the surgeon on the amount of load applied to the locking tack. An audible tone indicates when the correct pressure range is achieved to allow fixation of the tack to the nail. The ulnar nail and locking tack implants are composed of PEEK-Optima® polymer material and implant grade stainless steel. Locking of the tack to the nail creates a fixed angle construct that provides rotational alignment, torsional stability and axial control of the fractured ulna.
Indications for Use:	The Synthes Synsonic Ulna Nail System is intended to treat shaft fractures of the ulna, impending pathological fractures, malunions, and nonunions.

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Substantial Equivalence:	The summary information presented supports the substantial equivalence of the Synthes Synsonic Ulna Nail System to the predicate devices. The proposed system has the same intended use, similar indications for use and employs the same technology. Bench testing was conducted on the subject device construct to support substantial equivalence to the predicate devices including: • Static Cantilever Bend Testing • Cyclic Torsion Testing • Tack Removal Testing • Nail Removal Testing Design verification testing was conducted as part of the risk analysis to ensure the safe use of the subject device. This testing included: • Thermal Profile Testing: Conducted to analyze temperatures induced by the welding cycle and compared to criteria for thermal bone injury documented in clinical literature. The ultrasonic generator, handpiece, and footswitch components the proposed Synsonic Ulna Nail System were evaluated for electrical safety in accordance with the IEC 60601-1. The testing evaluated all of the components of proposed system, including the Synthes Synsonic Ultrasonic Generator, Handpiece, and Footswitch. The results of the bench testing indicate that the performance of the proposed Synsonic Ulna Nail System support its substantial equivalence to the predicate devices and will present no new issues with regard to safety or effectiveness. Additionally, the results of the safety tests conducted on the subject system met the established criteria and conform to the requirements of the relevant standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 31, 2014

Synthes
Ms. Angela F. Lassandro
Regulatory Affairs Manager
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K131984
Trade/Device Name: Synthes Synsonic Ulna Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: March 7, 2014
Received: March 10, 2014

Dear Ms. Lassandro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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5.0 - Indications for Use Statement

510(k) Number (if known): K131984

Device Name: Synthes Synsonic Ulna Nail System

Indications for Use:

The Synthes Synsonic Ulna Nail System is intended to treat shaft fractures of the ulna, impending pathological fractures, malunions, and nonunions.

Prescription Use ___X___ (Per 21 CFR 801.109) AND/OR Over-The-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices